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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,022	06/19/2003	Brent C. Gerberding	02-458US01	5691

54953 7590 04/28/2011
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EXAMINER

GANESAN, SUBA

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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04/28/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/600,022	Applicant(s) GERBERDING ET AL.	
	Examiner SUBA GANESAN	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 21-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 2/8/2011 have been fully considered but they are not persuasive. Applicant's remarks and amendments are sufficient to overcome the previously applied rejection under 35 U.S.C. 112. However, examiner notes a new rejection of claims 3-7 under 35 U.S.C 112 has been applied.
2. Applicant's claim amendments, including "a second set" of radiopaque markers with a circumferential non-serpentine band at at least one end of the framework comprising at least one radiopaque marker is insufficient to overcome the cited prior-art references. Edwin teaches additional radiopaque markers for identifying the ends of a PTFE sleeve on a stent (fig. 5 and related description). These markers are considered a "second set" of radiopaque markers.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-20, 32-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to support the defining of the markers as a first set and a second set. Moreover, the specification does not

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describe comparison of a first marker region and a second marker region to define an orientation of the inner and outer covering in relation to at least one end of the framework.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3-7 refer to “the radiopaque marker.” This limitation is considered indefinite in light of Applicant’s most recent claim amendments requiring a first set of radiopaque markers and a second set of radiopaque markers. It is unclear which markers the dependent claims are now referring to.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims **1-20** and **32-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijay (U.S. Pat. No.: 6,340,366) in view of Edwin et al. (Pub. No.: US 2002/0095209) and Ventura (Pub. No.: US 2004/0044399), with supporting evidence from Wu 6,331,189.

8. Wijay teaches a stent comprising a single tubular framework (fig. 4, 11) having an outer surface and an inner surface and a plurality of interconnected struts 46, the

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struts comprising a plurality of serpentine bands (fig. 4, 11) and further comprising a generally linear connector strut 38 attaching a peak of one serpentine band to a trough of an immediately adjacent serpentine band at the respective apices of each of the peak and the trough. The respective apices are axially aligned and connected with each other in opposing directions such that the single tubular framework has no gaps between the respective apices of the immediately adjacent serpentine bands (fig. 4, 11). The opposing apices reduce a distance between the immediately adjacent serpentine bands and attach to the generally linear connector strut 38. The framework comprises an outer covering.

9. However, Wijay does not teach the use of an inner and outer covering of PTFE. Edwin teaches the use of an outer and inner covering of expanded PTFE (para. 6-7) for the purpose of encapsulating a stent with an extremely biocompatible material that causes little or no immunogenic reaction when placed in the human body. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent of Wijay with the expanded PTFE covering as taught by Edwin for the purpose providing an extremely biocompatible surface on the stent of Wijay. The combination of Wijay and Edwin would be the result of a combination of prior art components, which would have been made with known methods and would have yielded predictable results.

10. Wijay in combination with Edwin is explained supra. However, the combination lacks a radiopaque marker directly and only attached to the generally linear connector strut and disposed between the inner and outer covering. Ventura teaches radiopaque

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marker placement specifically on a connector strut (fig. 4B-C, for example), resulting in specific areas of visualization for the stent. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the combination of Wijay and Edwin with radiopaque markers placed on the generally linear connector struts as taught by Ventura for the purpose of providing adequate visualization of the stent device.

11. Edwin teaches the specific placement of radiopaque markers to identify the ends of a PTFE covering that does not encapsulate the entire stent (the covering is located in the middle of the prosthetic, fig. 5). Edwin thus teaches a circumferential non-serpentine band at at least one end of the framework (the PTFE covering) that has a radiopaque marker of a “second set” (fig. 5). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent graft combination of Wijay and Ventura with radiopaque marker placement as taught by Edwin, such that the ends of the PTFE covering of are clearly identified. Identification of the ends of the PTFE covering would assist the surgeon in addressing aneurysms and other conditions in which the PTFE covering serves a therapeutic purpose and would inherently define an orientation of the inner and outer covering in relation to the framework when compared with the first set of radiopaque markers.

12. Ventura teaches a wound radiopaque marker band that is embedded into the connector strut (fig. 4C). With respect to claim 5, crimping is considered an obvious means of attaching a radiopaque marker to a connector strut, and the coil of Ventura is broadly interpreted to be a “split tube” because of its tubular shape. This attachment

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means would have been obvious to one of ordinary skill in the art as a suitable alternative means of adding radiopaque markers to a stent body. With respect to claim 8, Ventura does not specifically teach disc-shaped radiopaque markers. However, disc-shaped radiopaque markers are well known in the art (Edwin et al. 2002/0095209, fig. 5 and para. 25-27; Wu 6,331,189, fig. 2 element 9). Changes in size and shape of a prior art element are considered to be obvious design choices that are well within the level of ordinary skill in the art at the time the invention was made, especially in light of teachings in the prior art for the specific disc-shape of the radiopaque marker.

13. Edwin teaches expanded PTFE grafts that are coextensive (para. 6-7).

14. The use of stents in cranial vessels is known in the art. If not inherent in Wijay and Cottone, Jr., (Wijay is silent as to the dimension of the stent; the disclosed stent is capable of being placed into a cranial vessel of any animal including rabbits, primates and elephants) use of the described stent to correct cranial vessel defects would have been obvious to one with ordinary skill in the art based on medical considerations.

15. The radiopaque marker of Ventura does not protrude beyond the outer or inner surface of the stent (fig. 4C). Cottone, Jr. teaches a graft that does not cover the entire stent. The adhesion method employed by Edwin is considered lamination.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID ISABELLA/
Supervisory Patent Examiner, Art
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/S. G./
Examiner, Art Unit 3774